Programmatic Environmental Assessment for Market Authorization of Republic Tobacco, LP "Abadie 1-1/2 Size, JOB 1.5 Gold, TOP Standard, Zig-Zag 1¼ Size French Orange, Rolling Standard, Zig-Zag King Size, Ventura Whites, Zig-Zag Kutcorners Slow Burning, JOB 1.0 Silver, TOP 1-1/2 Size, OCB Organic Hemp King Size Slim, OCB Ungummed, OCB Yellow Cigarette Papers with Tips, Zig-Zag White, JOB 1.0 Gold, JOB Tribal King Size, OCB Organic Hemp Single Wide, OCB Slim Long Cigarette Papers with Tips, JOB Single Wide (White), Abadie 1-1/4 Size, JOB Brown Double Wide, Abadie Single Width, OCB Organic Hemp 1-1/4 Size, JOB Brown 1-1/4, JOB Brown 1-1/2, JOB French White, JOB Double Wide Gold, JOB Cutcorners (White), JOB 1-1/4 (Orange), JOB 1-1/2 (White) 99¢, JOB 1.5 Slim Gold, JOB 1.5 Silver, JOB 1.25 Silver, JOB 1.25 Gold"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

March 17, 2017

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This programmatic environmental assessment (PEA) is for the marketing authorizations of multiple roll-your-own (RYO) cigarette papers manufactured by “Republic Tobacco, LP”. Information presented in the PEA is based on the submission referenced in Appendix 1, unless noted or referenced otherwise. This PEA has been prepared in accordance to 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

Republic Tobacco, LP

2. Address

2301 Ravine Way
Glenview, IL 60025

3. Manufacturer

(b) (4)

4. Description of Proposed Actions

These proposed actions are for FDA to issue marketing authorizations under section 910(a)(2) of the FD&C Act for the introduction of multiple roll-your-own (RYO) cigarette papers into interstate commercial distribution in the U.S. The authorization is based on the finding that these new products are substantially equivalent to their corresponding predicate products that were on the market as of February 15, 2007. The applicant intends to market both the new and corresponding predicate products concurrently after receiving market authorizations for the new products. However, the applicant intends to progressively replace existing predicate products on the market with the new products, which will be manufactured by a different secondary supplier.

4.1 Requested Action

Orders finding the listed tobacco products are substantially equivalent to the corresponding predicate products.

4.2 Need for Action

Republic Tobacco, LP wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the U.S. The applicant claimed that the new products differ only from the predicate products in ingredient levels (sec 910(a)(3)(A)(ii) of the FD&C Act). In addition, the applicant claimed that the new products and predicate products have identical product and packaging composition. After considering the substantial equivalence (SE) reports (SE0012908, SE0012912-SE0012936, SE0012938, SE0012946-SE0012952), the Agency shall issue an order pursuant to section 910(a)(2) of the FD&C Act when finding the new products to be substantially equivalent to the corresponding predicate products.

4.3 Identification of the New Tobacco Products that is the Subject of the Proposed Actions

4.3.1 Type of Tobacco Products

Roll-your-own (RYO) cigarette papers with or without tips

4.3.2 Product Names and Their Original STNs

The names of the new products are listed below, along with the original submission tracking numbers (STNs) and the names of the predicate products. See Appendix 1 for additional STNs associated with the new products and the predicate products.

STN	New Product	Predicate Product (Grandfathered Product)
SE0012908	Abadie 1-1/2 Size	Abadie 1-1/2 Size
SE0012912	JOB 1.5 Gold	JOB 1.5 Gold
SE0012913	TOP Standard	TOP Standard
SE0012914	Zig-Zag 1¼ Size French Orange	Zig-Zag 1¼ Size French Orange
SE0012915	Rolling Standard	Rolling Standard
SE0012916	Zig-Zag King Size	Zig-Zag King Size
SE0012917	Ventura Whites	Ventura Whites
SE0012918	Zig-Zag Kutcorners Slow Burning	Zig-Zag Kutcorners Slow Burning
SE0012919	JOB 1.0 Silver	JOB 1.0 Silver
SE0012920	TOP 1-1/2 Size	TOP 1-1/2 Size
SE0012922	OCB Ungummed	OCB Ungummed
SE0012923	OCB Yellow Cigarette Papers with Tips	OCB Yellow Cigarette Papers with Tips
SE0012924	Zig-Zag White	Zig-Zag White
SE0012925	JOB 1.0 Gold	JOB 1.0 Gold
SE0012928	OCB Slim Long Cigarette Papers with Tips	OCB Slim Long Cigarette Papers with Tips
SE0012929	JOB Single Wide (White)	JOB Single Wide (White)
SE0012930	Abadie 1-1/4 Size	Abadie 1-1/4 Size
SE0012931	JOB Brown Double Wide	JOB Brown Double Wide
SE0012932	Abadie Single Width	Abadie Single Width
SE0012934	JOB Brown 1-1/4	JOB Brown 1-1/4
SE0012935	JOB Brown 1-1/2	JOB Brown 1-1/2
SE0012936	JOB French White	JOB French White
SE0012938	JOB Double Wide Gold	JOB Double Wide Gold
SE0012946	JOB Cutcorners (White)	JOB Cutcorners (White)
SE0012947	JOB 1-1/4 (Orange)	JOB 1-1/4 (Orange)
SE0012948	JOB 1-1/2 (White) 99¢	JOB 1-1/2 (White) 99¢
SE0012949	JOB 1.5 Slim Gold	JOB 1.5 Slim Gold
SE0012950	JOB 1.5 Silver	JOB 1.5 Silver
SE0012951	JOB 1.25 Silver	JOB 1.25 Silver
SE0012952	JOB 1.25 Gold	JOB 1.25 Gold

STN	New Product	Predicate Product (Previously found SE)
SE0012921	OCB Organic Hemp King Size Slim	OCB Organic Hemp King Size Slim
SE0012926	JOB Tribal King Size	JOB Tribal King Size
SE0012927	OCB Organic Hemp Single Wide	OCB Organic Hemp Single Wide
SE0012933	OCB Organic Hemp 1-1/4 Size	OCB Organic Hemp 1-1/4 Size

4.3.3 Description of the Product Package

The packaging materials of the finished new products are identical to those of their corresponding predicate products. The new product packaging components consist of a cardboard booklet containing the cigarette rolling papers and filter tips. The booklets are enclosed in a cardboard retail box (Also see Appendix 1). Details of the package components and weights of each packaging component for the new products are described in Confidential Appendix 6.

4.3.4 Location of Manufacturing

(b) (4)

[redacted]

[1] Manufacturer address via Google Map. Accessed June 8, 2016.

The manufacturing facility of the new RYO cigarette paper supplier is located outside of the U.S. Additional information, including an aerial map of the location, is in Confidential Appendix 1.

4.3.5 Location of Use

Republic Tobacco, LP intends to distribute and sell the new tobacco product to consumers in the U.S.

4.3.6 Location of Disposal

Once used, the new tobacco products will be disposed of in landfills as municipal solid waste (MSW) or as litter in the same manner as the predicate products and any other RYO products. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates the distribution of waste from disposal after use will correspond to the pattern of the product use.

4.4 Modification(s) Identified as Compared to the Predicate Products

The applicant claims that a minimal change in ingredient levels is the only difference between the new products and their predicate products. The applicant would like to source a raw ingredient for the new products from a different supplier, and therefore would result in differences in component ingredient levels.

5. Environmental Introduction Due to the Proposed Actions

5.1 Introduction as a Result of Manufacturing the New Tobacco Products

5.1.1 Tobacco Products Imported from France

Tobacco Import and Tobacco Market Volumes. According to the U.S. International Trade Commission (USITC), the import of tobacco products to the U.S. from France has increased from 1,889 metric tons in 2007 to 8,588 metric tons in 2016 (Figure 2).[2] When examining the change in import of cigarette rolling paper in the form of booklets to the U.S. from France over the same period of time, there was a significant decrease from 792 metric tons in 2007 to 533 metric tons in 2016 (Figure 3).[2]

The cigarette rolling paper in the form of booklets imported to the U.S. from France in 2016 represented 6.2% of the total amount of tobacco products imported from France in 2016.

[2] Unit is defined by the United States International Trade Commission, available at: http://dataweb.usitc.gov/. Accessed on February 17, 2017.

Figure 2. Total Tobacco Products Imported from France into the U.S. 2000-2016[2]

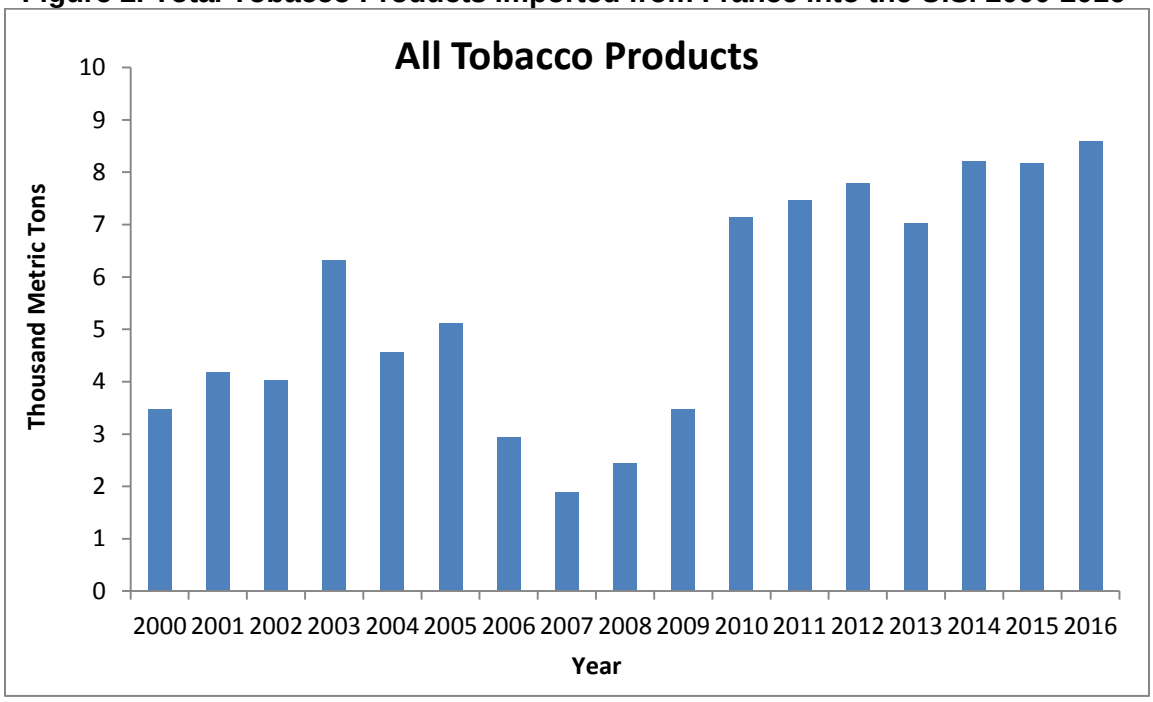
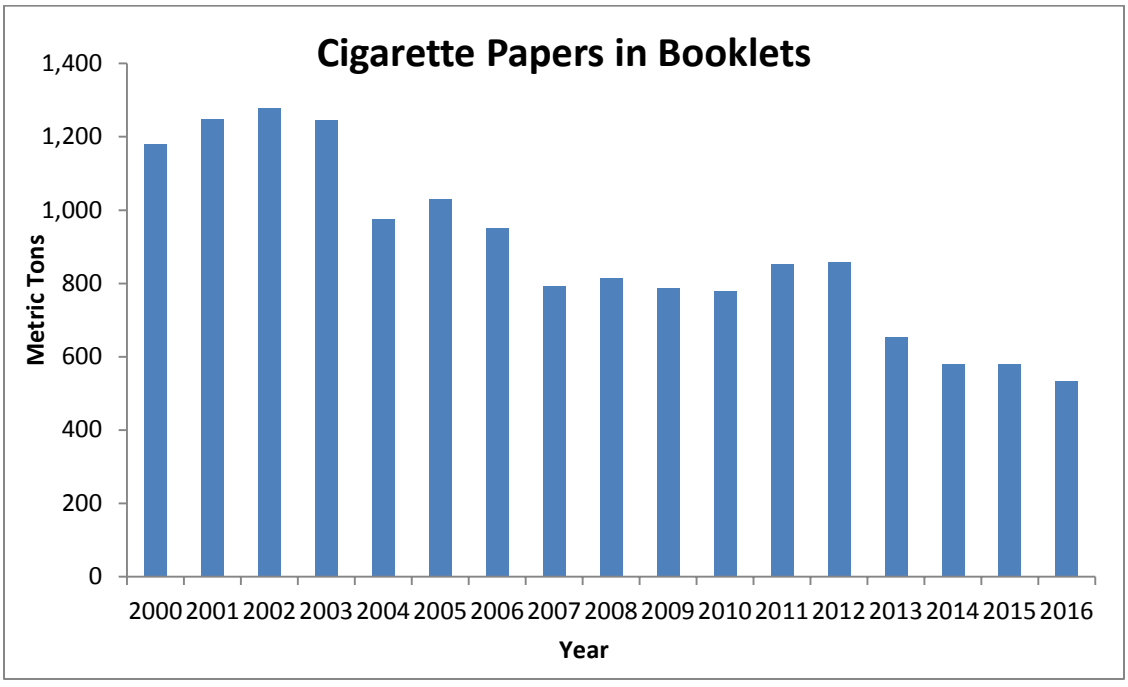


Figure 3. U.S. Import of Cigarette Papers in the Form of Booklets from France in 2000-2016[2]



5.1.2 Environmental Introduction from Manufacturing the New Tobacco Products

Introduction from Manufacturing the New Products in the Proposed Actions. The Agency anticipates the waste generated as a result of manufacturing the new RYO tobacco products will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other RYO tobacco products manufactured in France. In addition, although initially the new and corresponding predicate products will be simultaneously marketed, eventually the applicant intends to replace the predicate products with the new products (Appendix 1). The new products will also compete with other currently marketed RYO cigarette paper products. Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new products. There has been a general decline in cigarette rolling paper import from France from 1,180 metric tons in 2000 to 533 metric tons in 2016. Therefore, the Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the production of all cigarette rolling papers.

Based on information in the SE Reports, the only difference between the new products and the predicate products is in ingredient levels. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products.

The applicant provided the first- and fifth-year market volumes for the new products (Confidential Appendix 3). Comparing the projected market volume of the new products with the forecasted market volume of all tobacco products imported into the U.S. from France in 2017 and 2021, the cumulative projected market volumes of the new products are a small fraction of the total forecasted market volumes in 2017 and 2021 (Appendix 3 and Confidential Appendix 3). Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed.

The manufacturing facility is located in France and the applicant stated that the facility is in compliance with applicable French environmental laws and regulations. The applicant also stated that the RYO paper and tips are produced from renewable and sustainable resources and their manufacture does not appear to threaten any endangered species or critical habitat.

In 2014, the total greenhouse gas (GHG) emissions generated in the U.S. was estimated at 6,870 million metric tons of CO_2 equivalent (CO_2 Eq.). One of the primary sources of the total GHG emissions include the industry sector, which generated 22% of the 2015 GHG emissions(*1*). GHG emissions from industry originate mainly from burning fossil fuels for energy and certain chemical reactions to produce goods from raw materials. The U.S. manufacturing sector generated approximately 1,261 million metric tons of CO_2 Eq. in 2006(*2*). EPA released a final rule stating an expectation of methane emission reduction by an estimated 334,000 metric tons, the equivalent of reducing 8.2 million metric tons of CO_2 in 2025(*4*). Because the new products will ultimately replace the predicate products and compete with other currently marketed RYO products, no addition of GHG emissions is anticipated.[3] In addition, the applicant

[3] A qualitative analysis is recommended pursuant to the Council of Environmental Quality (CEQ) "Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews" when Agencies lack of tools, methodologies, or data inputs to qualify Greenhouse gas emission. See Reference #17.

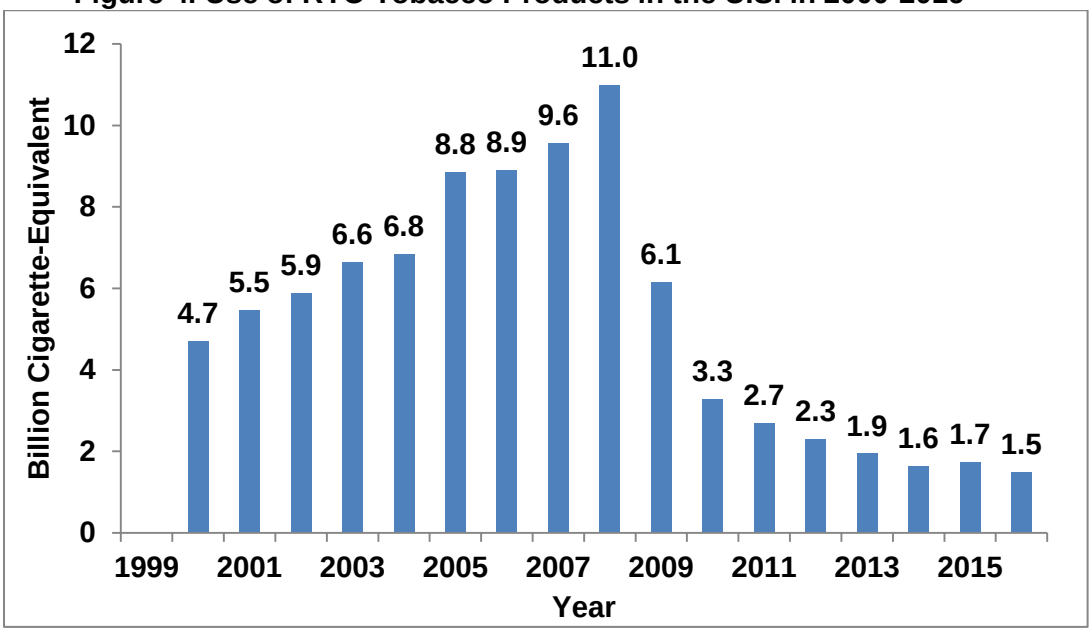
stated that the manufacturing facility abides by all applicable French Regional and Federal emissions regulations and requirements.

5.2 Environmental Introduction as a Result of Use of the New Tobacco Products

5.2.1 Use of the RYO Tobacco Products in the U.S.

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of RYO tobacco products in the U.S. increased from 4.7 billion cigarette-equivalents in 2000 to 11.0 billion cigarette-equivalents in 2008. This was followed by a decrease in use from 6.1 billion cigarette-equivalents[4] in 2009 to 1.5 billion cigarette-equivalents in 2016 (Figure 4) (*5, 6*).

Figure 4. Use of RYO Tobacco Products in the U.S. in 2000-2016[4]



5.2.2 Environmental Introduction from Use of the New Products

The applicant ultimately intends to replace, over time, the predicate products with the new products after receiving market authorizations for the new products. Additionally, because the new products are expected to compete with other RYO products on the market, the Agency anticipates minimal or no net increase in the use of all RYO products. Subsequently, the Agency does not anticipate new substances to be released into the environment as a result of use of the new RYO products, relative to the substances released by the predicate products, and other RYO products, already on the market. As noted, the only difference between the new products and corresponding predicate tobacco products is in ingredient levels. During use, the new products are burned to ash, carbon dioxide, and water vapor, as well as products of incomplete combustion such as carbon monoxide. These combustion products from

[4] The calculated cigarette-equivalence data is based on the conversion rate in the Master Settlement Agreement is that 0.0325 oz. (0.9 g) of tobacco equals to one cigarette. See Reference #5.

the new products are released in a similar manner to their predicate products and other RYO cigarette rolling paper products.

5.3 Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Products

The environmental consequences resulting from disposal following use of RYO cigarette rolling paper and tips are a) disposal of packaging, b) discarding of the used RYO tobacco products, and c) greenhouse gas emissions.

5.3.1 Disposal Following Use of RYO Rolling Cigarette Paper and Tips

a) Disposal of Packaging Material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the U.S., and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 5 and 6). Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), out of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW generated, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery(*7*).

Figure 5. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960-2014

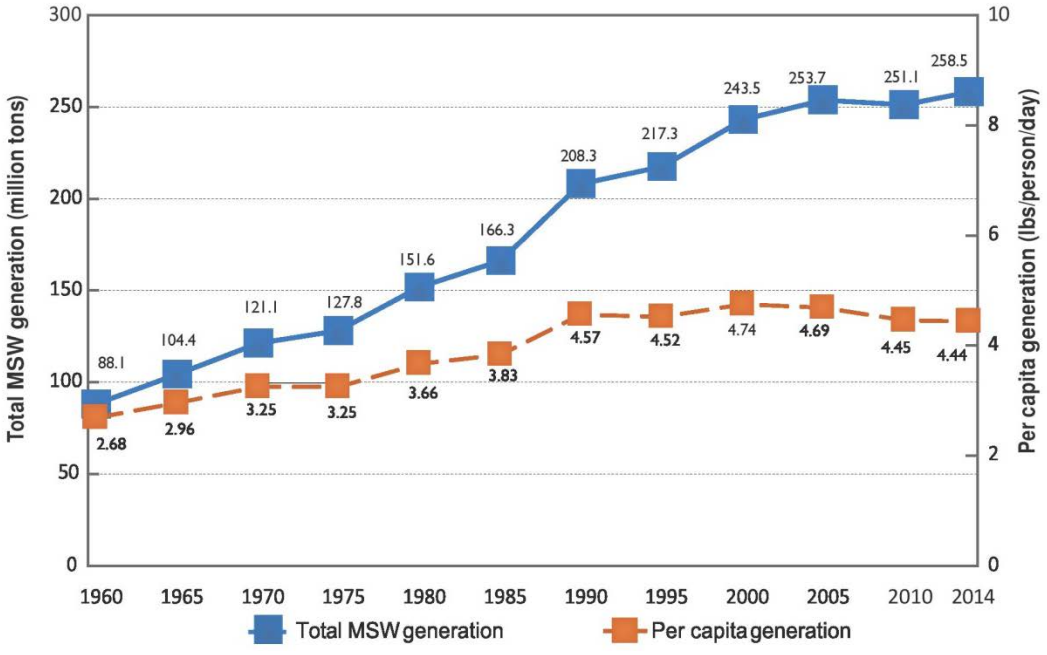
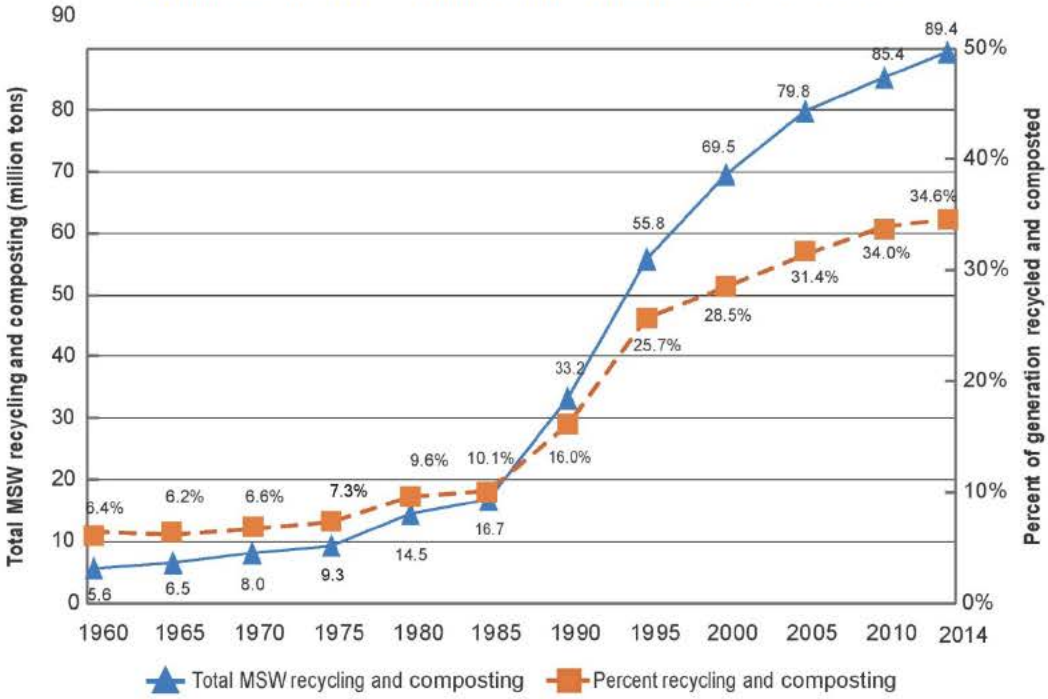


Figure 6. MSW Recycling Rates in the U.S., 1960-2014



b) Disposal of Used RYO Tobacco Products Following Use

Used RYO tobacco products are usually disposed of in MSW landfills or as litter. When discarded as litter, the spent products are likely to move by run-off to the ocean and eventually decompose. When discarded as MSW, the products would enter landfills. The Agency utilized the historical data for use of RYO tobacco products in the U.S. to forecast the future use of RYO tobacco products and calculate the projected tobacco waste accordingly (Appendix 3). Assuming that all used RYO tobacco products will be disposed of as MSW, the estimated waste of used RYO tobacco products is a fraction of a percent of the total 258.46 million tons (234.47 million metric tons) of projected MSW to be generated in the U.S. Comparing the projected market volume of the new products with the forecasted total U.S. MSW, the projected waste generated from use of the new products is negligible.

Forecast of Waste of Used RYO Tobacco Products as Compared to Total MSW Forecast in the U.S.		
Year	**Projected Use (Equivalent to Projected Waste) of RYO Tobacco Products in the U.S. (Billion Cigarette-Equivalent)[a]**	**Percent of Projected Waste of RYO Tobacco Products to Total MSW Forecasted in the U.S. (%)[5]**
1st Year		(b) (4)
5th Year		

[a] See Appendix 3

[5] RYO Tobacco Products in percentage: 1st Year = (b) (4)

5th Year =

c) Greenhouse Gas Emissions

The used RYO tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce greenhouse gases. According to the most recent MSW trend assessment by U.S. EPA, from the paper and paperboard waste generated in 2014, 64.7% was recycled, leaving 28.4% disposed of in MSW landfills and 6.9% combusted(*7*).

Global methane emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related methane emissions in the U.S., releasing an estimated 133.1 million metric tons of CO_2 Eq., accounting for approximately 18.2% of these emissions in 2014 (*3*). Methane is a potent greenhouse gas (GHG) that has a global warming potential of 28-36 times greater than CO_2, and has an atmospheric life of about 12 years. The decomposition of landfill waste produces approximately 50% biogenic CO_2 and 50% methane (CH_4), by volume, as well as trace amounts of non-methane organic compounds and volatile organic compounds. However, only CH_4 generation and emissions are estimated and reported for landfills, a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines(*8*). As mentioned previously, in 2014, MSW landfills generated roughly 133.1 MMT CO_2 Eq. of CH_4 emissions(*3*). Because the new products are intended to ultimately replace the corresponding predicate products and the waste generated from the new products is anticipated to comprise an infinitesimal fraction of the total MSW, the greenhouse gas emitted from waste associated with the new products is negligible.

5.3.2 Environmental Introduction from Disposal Following Use of the New Products

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other RYO cigarette rolling paper, tips, and any other RYO tobacco products that are currently being marketed. After using the new products, the users may dispose of or recycle the packaging material. Users may also discard the combusted tobacco and other ingredients (tips), as discussed above, as MSW or litter.

To determine the amount of waste due to disposal of packaging material and product material, the Agency used the projected market volumes in the first and fifth years after issuance of an authorization order for the new products. The calculated waste of the packaging materials and product materials of the new products were determined to be miniscule compared to the forecasted MSW to be generated in the U.S. (Confidential Appendix 6). In addition, paper components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

As previously discussed, because the new RYO rolling cigarette paper and tips will compete with other similar RYO tobacco products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfill is not anticipated due to the proposed actions.

The waste generated from using the new products is expected to make up a negligible fraction of the total MSW; no additional control of greenhouse gas emissions is anticipated in the landfills(*9*).

6. Fate of Materials Released into the Environment Due to the Proposed Actions

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment because the new products are anticipated to be manufactured, used, and disposed of in the same way as other RYO tobacco products, including rolling cigarette paper and tips. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other RYO tobacco products, including rolling cigarette paper and tips, manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use (Confidential Appendix 2) .

7. Environmental Effects of New Materials Released into the Environment due to the Proposed Actions

The applicant stated that the manufacturing operation is in compliance with all local, state and federal environmental laws. Therefore, cumulative introduction of materials released into the environment is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

As discussed above, the amount of materials anticipated to enter the environment due to the manufacturing and use of the new products are small fractions when compared to that of the projected RYO tobacco products imported from France and used in the U.S. The Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all RYO tobacco products. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction of the total forecasted MSWs in the U.S. Consequently, no new substances or new type of emissions are expected to be released, and therefore no new environmental controls are needed. No new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The new products will eventually replace corresponding predicate products and will compete with other currently marketed RYO tobacco products. The applicant also stated that the proposed actions will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total RYO market volumes in the U.S., the Agency found that the projected market volumes of the new products are a small fraction of the total forecasted market volume in 2017 and 2021. Because the new products are intended to eventually replace the corresponding predicate products, no increase of overall RYO tobacco product market volume and no net increase of energy use will be expected from the proposed actions. The applicant stated that all ingredients used to manufacture the new products, as well as the corresponding predicate products, are from renewable and sustainable resources. Accordingly, no additional use of resources and energy is anticipated.

9. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for the new products and the use as RYO. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Actions

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco products in the U.S. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products as the predicate products (Confidential Appendices 3 and 4) and many similar RYO tobacco products would continue to be marketed.

Alternative B (Proposed actions): There is no substantial environmental effect due to the proposed actions of authorizing the new products (Confidential Appendix 3) and associated manufacture, use, and disposal following use of the new tobacco products.

Therefore, the difference between the environmental impacts of these two alternatives is negligible, or non-existent.

11. List of Preparers

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment.

Preparers:

Catherine W. McCollum, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Biochemistry and Cell Biology
- Experience: 10 years in various scientific activities
- Expertise: NEPA analysis, environmental impact analysis, ecotoxicity, developmental toxicology

ITC Data Preparer:

Gregory G. Gagliano, M.S., Center for Tobacco Products
- Education: M.S. in Environmental Science
- Experience: 34 years in Environmental Toxicology and Risk Assessment
- Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

RYO Tobacco Products Projection Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Plant Molecular Biology and Virology
- Experience: 23 years in various scientific activities
- Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA implementation

Reviewers:

Gregory G. Gagliano, M.S., Center for Tobacco Products
- Education: M.S. in Environmental Science
- Experience: 34 years in Environmental Toxicology and Risk Assessment

Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

12. List of Agencies and Persons Consulted

Not applicable.

13. Appendix List

Appendix 1: Submission Tracking Numbers for the SE Reports and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)
Appendix 2: Forecast of All Tobacco Products Imported into the U.S. from France
Appendix 3: Forecast of Use of RYO Tobacco Products in the U.S.

14. Confidential Appendix List

Confidential Appendix 1: Location of the RYO Cigarette Paper Manufacturing Facility
Confidential Appendix 2: Modifications between New and Corresponding Predicate Products
Confidential Appendix 3: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products
Confidential Appendix 4: Comparison of the Current-Year Market Volume for the Predicate Products with Total RYO Tobacco Products Used in the U.S.
Confidential Appendix 5: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total RYO Tobacco Products Used in the U.S.
Confidential Appendix 6: The First- and Fifth-Year Projection of Paper and Cardboard Waste of Packaging Materials and Product Materials Associated with Marketing the Products

15. References

1. U.S. EPA. Draft Report: Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2014. EPA 430-P-17-001. Issued February 15, 2017. Available at https://www.epa.gov/sites/production/files/2017-02/documents/2017_complete_report.pdf. Accessed February 28, 2017.
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9. Council of Environmental Quality. Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews. Available at https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/ghg-guidance. Accessed December 1, 2016.

APPENDIX 1

Submission Tracking Numbers for the SE Reports and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

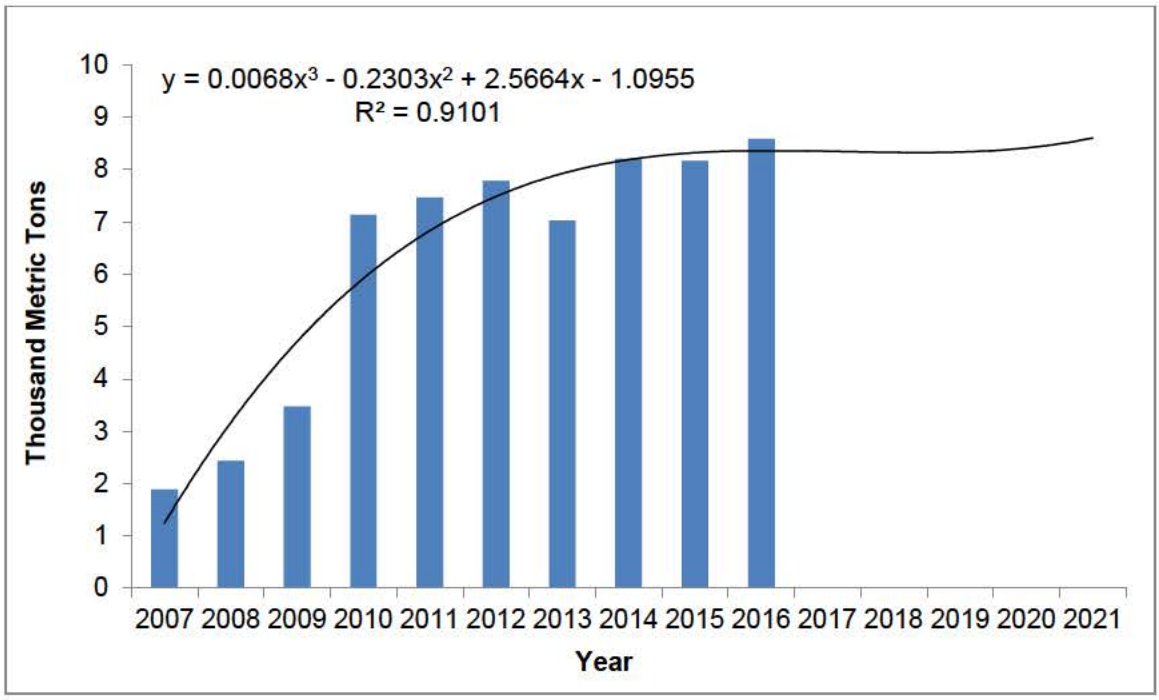
STN	Product Name	Product	Leaves per Booklet	Booklets per Box	Boxes per Shipping Case	Tips per Booklet	Amendments
SE0012908	Abadie 1-1/2 Size	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012912	JOB 1.5 Gold	New	24	24	40	0	SE0013796, SE0013846
		Predicate	24	24	40	0	
SE0012913	TOP Standard	New	100	24	40	0	SE0013796, SE0013846
		Predicate	100	24	40	0	
SE0012914	Zig-Zag 1¼ Size French Orange	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012915	Rolling Standard	New	50	24	40	0	SE0013796, SE0013846
		Predicate	50	24	40	0	
SE0012916	Zig-Zag King Size	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012917	Ventura Whites	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012918	Zig-Zag Kutcorners Slow Burning	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012919	JOB 1.0 Silver	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012920	TOP 1-1/2 Size	New	24	24	40	0	SE0013796, SE0013846
		Predicate	24	24	40	0	
SE0012921	OCB Organic Hemp King Size Slim	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012922	OCB Ungummed	New	150	24	40	0	SE0013796, SE0013846
		Predicate	150	24	40	0	
SE0012923	OCB Yellow Cigarette Papers with Tips	New	24	24	40	24	SE0013796, SE0013846
		Predicate	24	24	40	24	
SE0012924	Zig-Zag White	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012925	JOB 1.0 Gold	New	48	24	40	0	SE0013796, SE0013846
		Predicate	48	24	40	0	
SE0012926	JOB Tribal King Size	New	32	50	20	0	SE0013796, SE0013846
		Predicate	32	50	20	0	
SE0012927	OCB Organic Hemp Single Wide	New	100	24	40	0	SE0013796, SE0013846
		Predicate	100	24	40	0	
SE0012928	OCB Slim Long Cigarette Papers with Tips	New	24	24	40	24	SE0013796, SE0013846
		Predicate	24	24	40	24	
SE0012929	JOB Single Wide (White)	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012930	Abadie 1-1/4 Size	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	

STN	Product Name	Product	Leaves per Booklet	Booklets per Box	Boxes per Shipping Case	Tips per Booklet	Amendments
SE0012931	JOB Brown Double Wide	New	24	24	40	0	SE0013796, SE0013846
		Predicate	24	24	40	0	
SE0012932	Abadie Single Width	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012933	OCB Organic Hemp 1-1/4 Size	New	50	24	40	0	SE0013796, SE0013846
		Predicate	50	24	40	0	
SE0012934	JOB Brown 1-1/4	New	24	24	40	0	SE0013796, SE0013846
		Predicate	24	24	40	0	
SE0012935	JOB Brown 1-1/2	New	24	24	40	0	SE0013796, SE0013846
		Predicate	24	24	40	0	
SE0012936	JOB French White	New	24	24	40	0	SE0013796, SE0013846
		Predicate	24	24	40	0	
SE0012938	JOB Double Wide Gold	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012946	JOB Cutcorners (White)	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012947	JOB 1-1/4 (Orange)	New	24	24	40	0	SE0013796, SE0013846
		Predicate	24	24	40	0	
SE0012948	JOB 1-1/2 (White) 99¢	New	24	24	40	0	SE0013796, SE0013846
		Predicate	24	24	40	0	
SE0012949	JOB 1.5 Slim Gold	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012950	JOB 1.5 Silver	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012951	JOB 1.25 Silver	New	32	24	40	0	SE0013796, SE0013846
		Predicate	32	24	40	0	
SE0012952	JOB 1.25 Gold	New	24	24	40	0	SE0013796, SE0013846
		Predicate	24	24	40	0	

APPENDIX 2

Forecast of All Tobacco Products Imported into the U.S. from France

To evaluate the environmental impact of the proposed actions due to import of the new products, historical data regarding the import of all tobacco products from France into the U.S. from 2007 to 2016 was used to forecast the manufacture of RYO tobacco products[6]. This was achieved by using one best-fit polynomial trend line with the R^2 value of 0.9101. Accordingly, the forecasted amount of all tobacco products to be imported from France into the U.S. is estimated to be 8,319 metric tons in 2017 and 8,533 metric tons in 2021. The amount of all tobacco products imported from France into the U.S. is estimated at 8,588 metric tons in 2016.



Year[7]	All Tobacco Products Imported from France (Metric Tons)
Current Year (2016)	8,588
1st Year (2017)	8,319
5th Year (2021)	8,533

[6] Forecast trend lines extrapolated from USITC data. USITC data is available from http://dataweb.usitc.gov/. Accessed February 17, 2017.

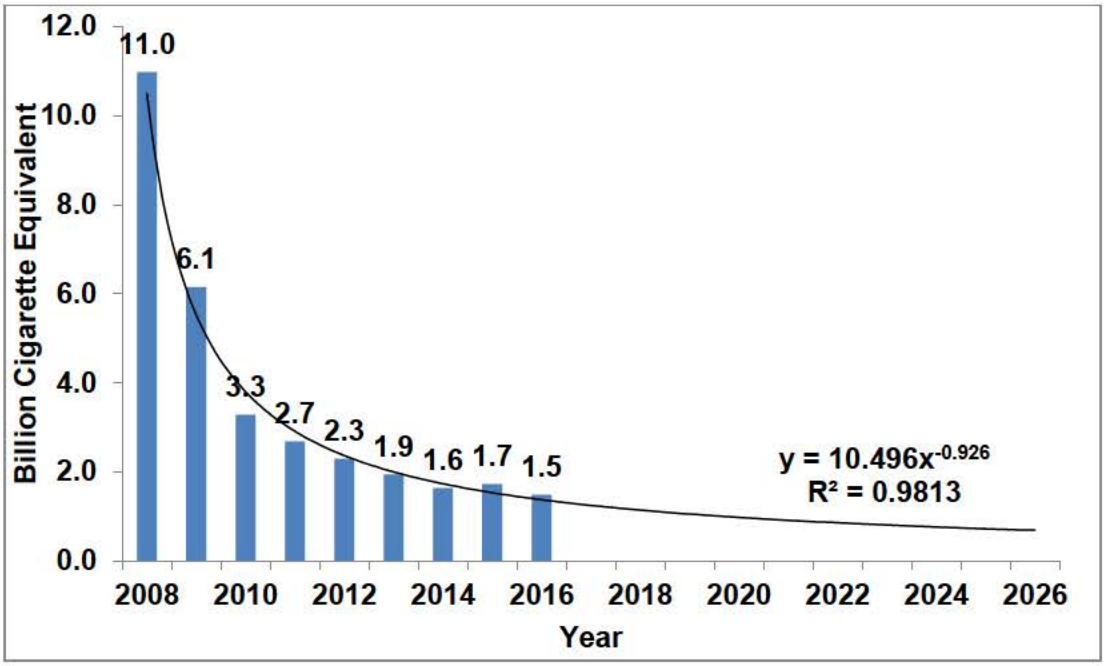
[7] 1st Year (2017) in thousand tons = $[0.0068 \times (11^3)] - [0.2303 \times (11^2)] + (2.5664 \times 11) - 1.0955 = 8.319$
5th Year (2021) in thousand tons = $[0.0068 \times (15^3)] - [0.2303 \times (15^2)] + (2.5664 \times 15) - 1.0955 = 8.533$

APPENDIX 3

Forecast of Use of RYO Tobacco Products in the U.S.

To evaluate the environmental impact of the proposed actions due to use of the new products, the Agency utilized the historical data of use in 2008–2016 to forecast the use of RYO tobacco products in the U.S. This was achieved by using one best-fit power trend line with the R^2 value of 0.9813.[8]

Using trend lines, the forecast of use of RYO tobacco products in the U.S. was estimated mathematically. Accordingly, the forecasted amount of RYO tobacco products to be used in the U.S. is estimated to be 1.2 billion cigarette-equivalents (1,120 metric tons) in 2017 and 0.9 billion cigarette-equivalents (820 metric tons) in 2021.[9] The amount of RYO tobacco products used in the U.S. is estimated to be 1.5 billion cigarette-equivalents (1,334 metric tons) in 2016.



Year[10]	RYO Tobacco Products (Billion Cigarette-Equivalent)	RYO Tobacco Products (Metric Tons)
Current Year	1.5	1,334
1st Year	1.2	1,120
5th Year	0.9	820

[8] Forecast trend lines extrapolated from TTB data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed March 15, 2017.

[9] Billion cigarette-equivalent value is calculated based on the assumption that approximately 0.9 grams of tobacco is used per cigarette. Billion cigarette-equivalent = $\frac{(X \text{ million pounds tobacco} \times 10^6)\times(\frac{453.59\text{ g}}{0.9\text{ g}})}{10^9}$

[10] 1st Year in billion cigarette-equivalent = 10.496 x 10EXP(-0.926) = 1.2
5th Year in billion cigarette-equivalent = 10.496 x 14EXP(-0.926) = 0.9

CONFIDENTIAL APPENDIX 1

Location of the RYO Cigarette Paper Supplier Manufacturing Facility

The new RYO cigarette papers will be manufactured at the following paper mill:

(b) (4)

CONFIDENTIAL APPENDIX 2

Modifications between New and Corresponding Predicate Products

The differences between the new and corresponding predicate products lie in the levels of paper ingredients and in the addition of cationic starch. The ingredient level differences do not result in a significant impact to the environment as these are ingredients commonly used in other RYO tobacco products. Moreover, the addition of cationic starch as an ingredient in the new products will not introduce new materials to the environment because the ultimate substance~~s~~ left after burning is carbon.

SE Report	Component	Ingredient	Function	Quantity (mg/leaf)		%Change
				New Product	Predicate Product	
SE0012908	Paper	(b) (4)	Fiber	(b) (4)		↓ 3
			Filler			↑ 6
			Adhesive			↑ 150
			Binder			(--)[12]
			Adhesive			(--)
			Processing Aid			(--)
SE0012912	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 159
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012913	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 7
			Binder			(--)
			Adhesive			(--)
SE0012914	Paper		Fiber			↓ 2
			Filler			↑ 7
			Adhesive			↑ 27
			Binder			(--)
			Adhesive			(--)

[11] The applicant stated that (-) means that it does not apply to particular ingredient.

[12] (--) means that % change could not be calculated since the applicant did not provide the exact quantities of the ingredients in either the new or predicate products.

[13] The applicant stated that PPM means that the ingredient is present in parts per million quantities. However, the exact amounts were not reported.

SE Report	Component	Ingredient	Function	Quantity (mg/leaf)		%Change
				New Product	Predicate Product	
		(b) (4)	Adhesive	(b) (4)		(--)
SE0012915	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 4
			Adhesive			(--)
			Binder			(--)
SE0012916	Paper		Fiber			↓ 2
			Filler			↑ 7
			Adhesive			↑ 26
			Binder			(--)
			Adhesive			(--)
			Adhesive			(--)
SE0012917	Paper		Fiber			↓ 1
			Filler			↑ 6
			Adhesive			↓ 26
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012918	Paper		Fiber			↓ 1
			Filler			↑ 6
			Adhesive			↓ 23
			Binder			(--)
			Adhesive			(--)
			Adhesive			(--)
SE0012919	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 150
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012920	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 159
			Binder			(--)
			Adhesive			(--)

SE Report	Component	Ingredient	Function	Quantity (mg/leaf)		%Change
				New Product	Predicate Product	
		(b) (4)	Processing Aid	(b) (4)		(--)
SE0012921	Paper		Fiber			↓ 0
			Filler			↓ 81
			Adhesive			(--)
			Binder			(--)
			Processing Aid			(--)
SE0012922	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 156
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012923	Paper		Fiber			↑ 2
			Filler			↓ 87
			Adhesive			(--)
			Binder			(--)
			Adhesive			(--)
	Tip		Processing Aid			0
			Processing Aid			0
			Processing Aid			0
			Processing Aid			0
			Processing Aid			0
SE0012924	Paper		Fiber			↓ 3
			Filler			↑ 21
			Adhesive			↓ 9
			Binder			(--)
			Adhesive			(--)
			Adhesive			(--)
SE0012925	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 150
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012926	Paper		Fiber			↓ 2

SE Report	Component	Ingredient	Function	Quantity (mg/leaf)		%Change
				New Product	Predicate Product	
		(b) (4)	Filler	(b) (4)		↑ 7
			Adhesive			↑ 1,500
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012927	Paper		Fiber			↓ 0
			Filler			↓ 80
			Adhesive			(--)
			Binder			(--)
			Processing Aid			(--)
SE0012928	Paper		Fiber			↓ 2
			Filler			↑ 7
			Processing Aid			(--)
			Adhesive			↑ 1,050
			Binder			(--)
			Adhesive			(--)
	Tip		Processing Aid			0
			Processing Aid			0
			Processing Aid			0
			Processing Aid			0
			Processing Aid			0
SE0012929	Paper		Fiber			↓ 1
			Filler			↑ 6
			Adhesive			↓ 25
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012930	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 146
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012931	Paper		Fiber			↓ 3
			Filler			↑ 7

SE Report	Component	Ingredient	Function	Quantity (mg/leaf)		%Change
				New Product	Predicate Product	
		(b) (4)	Adhesive	(b) (4)		↑ 158
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012932	Paper		Fiber			↓ 3
			Filler			↑ 6
			Adhesive			↑ 156
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012933	Paper		Fiber			↓ 0
			Filler			↓ 81
			Adhesive			(--)
			Binder			(--)
			Processing Aid			(--)
SE0012934	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 155
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012935	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 159
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012936	Paper		Fiber			↓ 2
			Filler			↑ 7
			Adhesive			↑ 27
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012938	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 158

SE Report	Component	Ingredient	Function	Quantity (mg/leaf)		%Change
				New Product	Predicate Product	
		(b) (4)	Binder	(b) (4)		(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012946	Paper		Fiber			↓ 1
			Filler			↑ 6
			Adhesive			↓ 23
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012947	Paper		Fiber			↓ 2
			Filler			↑ 7
			Adhesive			↑ 27
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012948	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 159
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012949	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 162
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012950	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 159
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012951	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 155

SE Report	Component	Ingredient	Function	Quantity (mg/leaf)		%Change
				New Product	Predicate Product	
		(b) (4)	Binder	(b) (4)		(--)
			Adhesive			(--)
			Processing Aid			(--)
SE0012952	Paper		Fiber			↓ 3
			Filler			↑ 7
			Adhesive			↑ 155
			Binder			(--)
			Adhesive			(--)
			Processing Aid			(--)

CONFIDENTIAL APPENDIX 3

The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products

STN	Unit	Current-Year Market Volume	First-Year Market Volume		Fifth-Year Market Volume	
		Predicate Product	New Product[14]	Predicate Product[15]	New Product[11]	Predicate Product[12]
SE0012908	Individual Leaves of Rolling Papers	(b) (4)				
	Metric Tons					
SE0012912	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012913	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012914	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012915	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012916	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012917	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012918	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012919	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012920	Individual Leaves of Rolling Papers					
	Metric Tons					

[14] Expected combined projected total market volume of both predicate and new products after market authorizations of the new products.

[15] Expected projected market volume if new products in the SE reports are not authorized for marketing.

STN	Unit	Current-Year Market Volume	First-Year Market Volume		Fifth-Year Market Volume	
		Predicate Product	New Product[11]	Predicate Product[12]	New Product[11]	Predicate Product[12]
SE0012921	Individual Leaves of Rolling Papers	(b) (4)				
	Metric Tons					
SE0012922	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012923	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012924	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012925	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012926	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012927	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012928	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012929	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012930	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012931	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012932	Individual Leaves of Rolling Papers					
	Metric Tons					

STN	Unit	Current-Year Market Volume	First-Year Market Volume		Fifth-Year Market Volume	
		Predicate Product	New Product[11]	Predicate Product[12]	New Product[11]	Predicate Product[12]
SE0012933	Individual Leaves of Rolling Papers	(b) (4)				
	Metric Tons					
SE0012934	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012935	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012936	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012938	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012946	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012947	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012948	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012949	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012950	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012951	Individual Leaves of Rolling Papers					
	Metric Tons					
SE0012952	Individual Leaves of Rolling Papers					
	Metric Tons					

CONFIDENTIAL APPENDIX 4

Comparison of the Current-Year Market Volume for the Predicate Products with Total RYO Tobacco Products Used in the U.S.

The current-year market volume of the predicate products occupying the U.S. market was compared to the use of total RYO tobacco in the U.S. (Appendices 2, 3, and Confidential Appendix 3). The percent of the total cigarette market occupied in the current year of marketing of the predicate products was calculated using the equation below[16]:

$$\text{2016 Market Occupation of Predicate Products (\%)} = \frac{\text{2016 Market Volume (metric tons)}}{\text{Use of RYO in the U.S.for 2016 (metric tons)}} \times 100\%$$

STN	Year	Import of Total Tobacco Products from France (Metric Tons)[17]	Use of Total RYO Tobacco in the U.S. (Metric Tons)[18]	Market Volume of Predicate Product (Metric Tons)[19]	Market Occupation of Predicate Product in the U.S. (%)
SE0012908	2016	8,588	1,334	(b) (4)	
SE0012912	2016	8,588	1,334		
SE0012913	2016	8,588	1,334		
SE0012914	2016	8,588	1,334		
SE0012915	2016	8,588	1,334		
SE0012916	2016	8,588	1,334		
SE0012917	2016	8,588	1,334		
SE0012918	2016	8,588	1,334		
SE0012919	2016	8,588	1,334		
SE0012920	2016	8,588	1,334		
SE0012921	2016	8,588	1,334		
SE0012922	2016	8,588	1,334		
SE0012923	2016	8,588	1,334		
SE0012924	2016	8,588	1,334		
SE0012925	2016	8,588	1,334		
SE0012926	2016	8,588	1,334		
SE0012927	2016	8,588	1,334		
SE0012928	2016	8,588	1,334		
SE0012929	2016	8,588	1,334		
SE0012930	2016	8,588	1,334		
SE0012931	2016	8,588	1,334		
SE0012932	2016	8,588	1,334		
SE0012933	2016	8,588	1,334		
SE0012934	2016	8,588	1,334		
SE0012935	2016	8,588	1,334		
SE0012936	2016	8,588	1,334		
SE0012938	2016	8,588	1,334		
SE0012946	2016	8,588	1,334		
SE0012947	2016	8,588	1,334		
SE0012948	2016	8,588	1,334		

[16] Each individual leaf of rolling paper is anticipated to be used in making a single cigarette unit. Therefore, one leaf of rolling paper is equal to one cigarette-equivalent.

[17] See Appendix 2.

[18] See Appendix 3.

[19] See Confidential Appendix 3.

STN	Year	Import of Total Tobacco Products from France (Metric Tons)[17]	Use of Total RYO Tobacco in the U.S. (Metric Tons)[18]	Market Volume of Predicate Product (Metric Tons)[19]	Market Occupation of Predicate Product in the U.S. (%)
SE0012949	2016	8,588	1,334	(b) (4)	
SE0012950	2016	8,588	1,334		
SE0012951	2016	8,588	1,334		
SE0012952	2016	8,588	1,334		

CONFIDENTIAL APPENDIX 5

Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total RYO Tobacco Products Used in the U.S.

The first- and fifth-year market volumes of the new products to occupy the U.S. market were determined by comparing the projected market volume of the new products to the forecasted use of total RYO tobacco in the U.S. (Appendices 2, 3, and Confidential Appendix 3). The percent of the total cigarette market occupied in the projected first and fifth year of marketing of the new products was calculated using the equations below[20]:

$$\text{First Year Market Occupation of New Products (\%)} = \frac{\text{First–Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of RYO in the U.S.for 2017 (metric tons)}} \times 100\%$$

$$\text{Fifth Year Market Occupation of New Products (\%)} = \frac{\text{Fifth–Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of RYO in the U.S.for 2021 (metric tons)}} \times 100\%$$

STN	Year	Forecasted Import of Total Tobacco Products from France (Metric Tons)[21]	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)[22]	Projected Market Volume of New Product (Metric Tons)[23]	Projected Market Occupation of New Product in the U.S. (%)
SE0012908	First-Year	8,319	1,120	(b) (4)	
	Fifth Year	8,533	820		
SE0012912	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012913	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012914	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012915	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012916	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012917	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012918	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012919	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012920	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012921	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012922	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012923	First-Year	8,319	1,120		

[20] Each individual leaf of rolling paper is anticipated to be used in making a single cigarette unit. Therefore, one leaf of rolling paper is equal to one cigarette-equivalent.

[21] See Appendix 2.

[22] See Appendix 3.

[23] See Confidential Appendix 3.

STN	Year	Forecasted Import of Total Tobacco Products from France (Metric Tons)[21]	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)[22]	Projected Market Volume of New Product (Metric Tons)[23]	Projected Market Occupation of New Product in the U.S. (%)
	Fifth Year	8,533	820	(b) (4)	
SE0012924	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012925	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012926	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012927	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012928	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012929	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012930	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012931	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012932	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012933	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012934	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012935	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012936	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012938	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012946	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012947	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012948	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012949	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012950	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012951	First-Year	8,319	1,120		
	Fifth Year	8,533	820		
SE0012952	First-Year	8,319	1,120		
	Fifth Year	8,533	820		

CONFIDENTIAL APPENDIX 6

The First- and Fifth-Year Projection of Total Waste of Packaging Materials and Product Materials Associated with Marketing the Products

To analyze the environmental effects from total waste due to the proposed actions, the Agency estimated the first- and fifth-year weights of the projected packaging and product materials waste (in metric tons) that are generated from disposal after use of the new products in 2017 and 2021. Projected paper waste generation is the summation of the projected booklet cover, cardboard box, used tip, "cigarette butt"[23], and shipping case waste generation of the new products:

$$\sum_{i=1}^{34} A_i = \sum_{i=1}^{34} (B_i + C_i + D_i + E_i + F_i)$$

$$B_i = \frac{G_i}{H_i} \times I \times Z$$

$$C_i = \frac{G_i}{H_i \times J_i} \times K \times Z$$

$$D_i = \frac{G_i}{H_i \times J_i \times L_i} \times M \times Z$$

$$E_i = G_i \times N_i \times Z$$

$$F_i = \frac{G_i \times P_i \times Q_i}{100} \times Z$$

$$P_i = \frac{27}{O_i} \times 100$$

A_i: Projected paper waste generation of the new products (metric tons)
B_i: Projected booklet cover waste generation of the new products (metric tons)
C_i: Projected retail cardboard box waste generation of the new products (metric tons)
D_i: Projected shipping case waste generation of the new products (metric tons)
E_i: Projected used tip waste generation of the new products (metric tons)
F_i: Projected "cigarette butt"[24] waste of the new products (metric tons)
G_i: Projected market volume of the new products (# individual leaves of rolling paper)
H_i: Number of individual leaves of rolling papers per booklet
I: Weight of booklet cover (grams)
J_i: Number of booklets per retail cardboard box
K: Weight of empty retail cardboard box (grams)
L_i: Number of retail cardboard boxes per shipping case
M: Weight of empty shipping case (grams)
N_i: Weight of tip (grams)
O_i: Length of rolling paper (millimeters)
P_i: Cigarette Butt Ratio (%)[25]
Q_i: Weight of rolling paper (milligrams per leaf)
Z: 1.0 x 10^{-6} metric tons/gram

[24] "Cigarette butt" in this PEA is defined as cigarette rolling paper containing remainder tobacco that is disposed of following use.

[25] ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed as solid waste following use.

	STN	
First Year	SE0012908	(b) (4)
	SE0012912	
	SE0012913	
	SE0012914	
	SE0012915	
	SE0012916	
	SE0012917	
	SE0012918	
	SE0012919	
	SE0012920	
	SE0012921	
	SE0012922	
	SE0012923	
	SE0012924	
	SE0012925	
	SE0012926	
	SE0012927	
	SE0012928	
	SE0012929	
	SE0012930	
	SE0012931	
	SE0012932	
	SE0012933	
	SE0012934	
	SE0012935	
	SE0012936	
	SE0012938	
	SE0012946	
	SE0012947	
	SE0012948	
	SE0012949	
	SE0012950	
	SE0012951	
	SE0012952	
	First-Year Total Paper Waste for New Products (metric tons)	(b) (4)

	STN	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
Fifth Year	SE0012908	(b) (4)																
	SE0012912																	
	SE0012913																	
	SE0012914																	
	SE0012915																	
	SE0012916																	
	SE0012917																	
	SE0012918																	
	SE0012919																	
	SE0012920																	
	SE0012921																	
	SE0012922																	
	SE0012923																	
	SE0012924																	
	SE0012925																	
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	SE0012938																	
	SE0012946																	
	SE0012947																	
	SE0012948																	
	SE0012949																	
	SE0012950																	
	SE0012951																	
	SE0012952																	
	Fifth-Year Total Paper Waste for New Products (metric tons)																	(b) (4)

Total Waste. The booklet cover, retail cardboard box, and shipping case are disposed of, recycled, or both as paper waste, while the tip and "cigarette butt" are disposed of as waste or litter. Estimation of generated total waste for the new products is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper products at 64.7% in the U.S., according to U.S. EPA(7). Therefore, if 100% of the tips and "cigarette

butts", and 35.3% of the booklets, retail cardboard boxes, and shipping cases are disposed of as waste based on the 2014 waste generation data in the U.S., the estimated cumulative total waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new products.[26]

If the entire packaging paper and cardboard waste is disposed of as waste, which is a more conservative approach, the projected cumulative total waste in the first and fifth years of marketing the new products is (b) (4) metric tons and (b) (4) metric tons, respectively. Even using this conservative approach, this is still a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. in 2014.

[26] At 35.3% disposal rate as paper waste (on booklets, cardboard boxes, and shipping cases) for the 1st Year (b) (4) *metric tons*; 5th Year, *metric tons*.